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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/722,292	11/25/2003	Richard A. Shimkets	11669.206USD1	9115

23552 7590 04/04/2007

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EXAMINER	
WHITEMAN, BRIAN A	
ART UNIT	PAPER NUMBER
1635	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/04/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/722,292	SHIMKETS ET AL.	
	Examiner	Art Unit	
	Brian Whiteman	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 January 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *50,51,53,63,65-67* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *50,51,53,63 and 65-67* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 50, 51, 53, 63, and 65-67 are pending.

Election/Restrictions

This application contains the limitation 'a fragment of the protein comprising a domain of the protein' in claim 50 drawn to an invention nonelected with traverse in Paper No. 7/14/06. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Priority

The cross-reference to parent applications on page 1 needs updated.

Claim Objections

Claim 50 is objected to because of the following informalities: the claim embraces non-elected embodiment (a fragment of the protein comprising a domain of the protein). Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 50, 51, 53, 63, 65-67 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 50, as best understood, is readable on a genus of ligands that is differently expressed in cardiac hypertrophy relative to normal cardiac tissue, wherein the ligand comprises a protein having at least 95% identity to a polypeptide encoded by SEQ ID NO: 9, wherein the genus of ligands is not claimed in a specific biochemical or molecular structure that could be envisioned by one skilled in the art at the time the invention was made are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 51, 53, 63, and 65-67, as best understood, is readable on a genus of CHAG polynucleotide encoding a protein having at least 95% identity to a polypeptide encoded by SEQ ID NO: 9 and/or genus of antisense nucleic acids, wherein the genus of CHAG polynucleotides and/or genus of antisense nucleic acids is not claimed in a specific biochemical or molecular structure that could be envisioned by one skilled in the art at the time the invention was made are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111 (Fed Cir. 1991), clearly states that:

> The applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is not claimed*." *Vas-Cath Inc. v. Mahurkar, 19USPQ2d at 1117*. The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." *Vas-Cath Inc. v. Mahurkar, 19USPQ2d at 1116*.

The instant specification contemplates a genus of molecules that bind to CHAG nucleic acids. The elected invention is directed to a molecule that binds to a ligand (nucleic acid encoding CH-9 (SEQ ID NO: 9). The specification further contemplates using the CHAG nucleic acids to produce proteins that bind to the molecule. However, the elected invention is directed to a molecule or antisense that inhibits expression of a CHAG polynucleotide comprising CH-9 (SEQ ID NO: 9) or a CHAG polynucleotide encoding a protein having 95% identity to a polypeptide encoded by SEQ ID NO: 9. The term "a protein having at least 95% identity to a polypeptide sequence encoded by SEQ ID NO: 9" in claim 50 is broader than a CHAG polynucleotide comprising SEQ ID NO: 9. Page 9 of the instant specification contemplates CH-9, as well as derivatives and analogs thereof and CH-9 has nucleotide sequence homology to mouse and human zyxin. Page 9 further recites: The invention relates to derivative and analogs of CH-9 proteins that are functionally active, i.e., they are capable of displaying one or more functional activities associated with a full-length (wild-type) protein. With respect to claims 50, 51, 53, 63, 65-66, there is a variation among species embraced by the claimed genus of molecules. For examples, the genus embraces nucleic acid encoding genomic DNA encoding

CH-9 from human, rat, mouse, rabbit, bear, monkey, etc. In addition, the instant specification does not disclose which nucleotides are considered essential for binding a molecule to the nucleic acid or fragment thereof. Furthermore, the instant specification does not disclose how to make the genus of agents and/or ligands. The elected invention embrace making and using catalytic RNA, ribozymes, chimeric RNA-DNA analogue, and antisense RNA that interfere with the function of the CH-9 nucleic acid such as DNA replication, transcription, translocation of the CH-9 to the site of protein translation, translation of protein from the CH-9 RNA, splicing of the CH-9 to yield one or more mRNA species, or catalytic activity which may be engaged in or facilitated by the CH-9. One skilled in the art can envision a sequence that hybridizes to a CHAG polynucleotide comprising SEQ ID NO: 9, but would be able to determine if the sequence had a function that was considered essential for the claimed genus of antisense nucleic acids or genus of ligands. Also, there is a variation among species of the claimed genus of antisense nucleic acids and/or ligands. For example, the genus of molecules embraces oligonucleotides that bind to introns and cap structures that are neither disclosed in the specification nor the prior art. In addition, the skilled artisan understands that human CH-9 gene with polymorphisms are embraced by the claimed genus that are not disclosed in the instant specification or prior art. Furthermore, the specification does not disclose how to make a sufficient number of species to represent the genus of claimed antisense nucleic acids and/or ligands. The mere contemplation of the claimed genus of antisense nucleic acids and/or ligands in the specification is not sufficient to support the present claimed invention directed to a genus of antisense nucleic acids and/or genus of ligands.

It is apparent that on the basis of applicants' disclosure, an adequate written description of the invention defined by the claims requires more than a mere statement that it is part of the invention and reference to potential methods and/or molecular structures of molecules that are essential for the genus of ligands and/or a genus of antisense nucleic acids and/or genus of a protein having at least 95% identity to a polypeptide sequence encoded by SEQ ID NO: 9 as claimed; what is required is the knowledge in the prior art and/or a description as to the availability of a representative number of species of biochemical or molecular structures of agents and/or molecules that must exhibit the disclosed biological functions as contemplated by the claims.

The mere contemplation of the claimed genus in the specification is not sufficient to support the present claimed invention directed to a genus of genus of ligands and/or antisense nucleic acids and/or a protein having at least 95% identity to a polypeptide sequence encoded by SEQ ID NO: 9. The claimed invention as a whole is not adequately described if the claims require essential or critical elements, which are not adequately described in the specification and which is not conventional in the art as of applicant's effective filing date. Claiming a genus of genus of ligands and/or antisense nucleic acids and/or a protein having at least 95% identity to a polypeptide sequence encoded by SEQ ID NO: 9 that must possess the biological properties as contemplated by applicants' disclosure without defining what means will do so is not in compliance with the written description requirement. Rather, it is an attempt to preempt the future before it has arrived. (See *Fiers v. Revel*, 25 USPQ2d 1601 (CAFC 1993) and *Regents of the Univ. Calif. v. Eli Lilly & Co.*, 43 USPQ2d 1398 (CA FC, 1997)). Possession may be shown by actual reduction to practice, clear depiction of the invention in a detailed drawing, or by

describing the invention with sufficient relevant identifying characteristics such that a person skilled in the art would recognize that the inventor had possession of the claimed invention. Pfaff v. Wells Electronics, Inc., 48 USPQ2d 1641, 1646 (1998). The skilled artisan cannot envision the detailed structure of a genus of genus of ligands and/or antisense nucleic acids and/or a protein having at least 95% identity to a polypeptide sequence encoded by SEQ ID NO: 9 that must exhibit the contemplated biological functions, and therefore, conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the structures and/or methods disclosed in the as-filed specification. Thus, in view of the reasons set forth above, one skilled in the art at the time the invention was made would not have recognized that applicant was in possession of the claimed invention as presently claimed.

Applicant's arguments filed 1/3/07 have been fully considered but they are not persuasive.

In response to applicant's argument that written description does not require the specification to describe the biochemical or molecule structure of the genus of molecules or how to make the genus of molecules, the argument is not found persuasive because the specification does not disclose how to make a genus of ligands and/or a genus of antisense nucleic acids and/or a genus of proteins having at least 95% identity to a polypeptide sequence encoded by SEQ ID NO: 9 and/or a genus of fragments of the protein comprising a domain of the protein. Univ. of Rochester v. G.D. Searle & Co., 358 F.3d 916, 927, 69 USPQ2d 1886, 1894-95 (Fed. Cir. 2004). A review of the specification reveals that a nucleic acid comprising CH-9 is essential to the function/operation of the claimed invention. In addition, a ligand or antisense is essential to the claimed invention. A search of the prior (Branch TIBS 23 45-50, 1998, Braasch et al.

Biochemistry 41 4503-4510, 2002, and Tamm et al. The Lancet 358 489-497, 2001) reveals that the claimed method is novel and unobvious. the claims are drawn to a genus, i.e., any of a variety if ligands, antisense nucleic acids, and a protein having at least 95% identity to a polypeptide sequence encoded by SEQ ID NO: 9 (CH-9). There is not actual reduction to practice of a single embodiment, i.e., assaying a ligand or antisense nucleic acid in an isolated cell comprising a protein having at least 95% identity to a polypeptide sequence encoded by SEQ ID NO: 9. The art indicates that there is substantial variation within each genus recited in the instant claims because there are a number of antisense nucleic acids, ligands, and a protein having at least 95% identity to a polypeptide sequence encoded by SEQ ID NO: 9 involved in the process steps of the claimed invention. One of skill in the art would not recognize that applicant was in possession of all of the various methods necessary to practice the claimed invention.

In response to applicant's argument that any molecule can be screened for binding to the ligand, the argument is not found persuasive because the products used in the method are drawn to a genus of ligands, antisense nucleic acids, and a protein having at least 95% identity to a polypeptide sequence encoded by SEQ ID NO: 9. "A definition by function alone "does not suffice" to sufficiently describe a coding sequence "because it is only an indication of what the gene does, rather than what it is."" Eli Lilly, 119 F.3 at 1568, 43 USPQ2d at 1406. See also Fiers, 984 F.2d at 1169-71, 25 USPQ2d at 1605-06. The claims are broad and read on virtually any nucleic acid. The art indicates that there is substantial variation within the genus because of the lack of teaching for what domains of a protein having at least 95% identity to a polypeptide

sequence encoded by SEQ ID NO: 9 are required for a ligand or protein that is differentially expressed in cardiac hypertrophy tissue relative to normal cardiac tissue.

Response to Arguments

Applicant's arguments, see pages 6-8, filed 1/3/07, with respect to new matter rejection have been fully considered and are persuasive. The rejection of claims 51-53 and 62-64 has been withdrawn because applicant has cited pages in the specification that sufficiently describe the claimed methods.

Applicant's arguments, see pages 9-10, filed 1/3/07, with respect to enablement rejection have been fully considered and are persuasive. The rejection of claims 50-53 and 62-64 has been withdrawn because the amendment to claims 50 and 51.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Whiteman whose telephone number is (571) 272-0764. The examiner can normally be reached on Monday through Friday from 6:30 to 4:00 (Eastern Standard Time), with alternating Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Douglas Schultz, PhD, SPE – Art Unit 1635, can be reached at (571) 272-0763.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Fax Center number is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Brian Whiteman